REMARKS

Pending claims

Claims 1-23 are currently pending,

Restriction Requirement

Applicants hereby elect, with traverse, to prosecute Group II(E), which includes and is drawn to Claims 3-6, 8, 10 and 11 as they relate to polynucleotide sequences encoding claimed polypeptide sequence SEQ ID NO:5, which sequences include the claimed polynucleotide sequence SEQ ID NO:19.

Applicants reserve the right to prosecute the subject matter of non-elected claims in subsequent divisional applications.

Both the restriction requirement and the obligation to elect a single sequence for prosecution imposed by the Examiner are traversed for at least the following reasons.

The unity of invention standard ***must*** be applied in national stage applications

Section 1850 of the Manual of Patent Examining Procedure (original 8th edition, published August, 2001) (hereinafter "MPEP") provides:

> ... [W]hen the Office considers international applications ... during the national stage as a Designated or Elected Office under 35 U.S.C. 371, PCT Rule 13.1 and 13.2 will be followed when considering unity of invention of claims of different categories without regard to the practice in national applications filed under 35 U.S.C. 111....
>
> In applying PCT Rule 13.2 to ... national stage applications under 35 U.S.C. 371, examiners should consider for unity of invention all the claims to different categories of invention in the application and permit retention in the same application for searching and/or preliminary examination, claims to the categories which meet the requirements of PCT Rule 13.2....

Id at page 1800-60 to -61.

MPEP section 1893.03(d) reiterates the Examiner's obligation to apply the Unity of Invention standard PCT Rule 13.2 instead of U.S. restriction/election of species practice:

> Examiners are reminded that unity of invention (not restriction) practice is applicable ... in national stage (filed under 35 U.S.C. 371) applications.

Id at page 1800-149, column 1.

Specific provisions of the Administrative Regulations Under the PCT and the corresponding provisions of the MPEP strongly support a finding of unity of invention among claims 1-4 and 10-11 in the present case

Unity of Invention is accepted as between claims to polypeptide sequences (claims 1-2 of Group I) and claims to the polynucleotide sequences which encode them (claims 3-4 and 10-11 of Group II)

Example 17, Part 2 of Annex B to the Administrative Instructions Under the PCT provides that unity of invention is accepted as between claims directed to a polypeptide and claims to polynucleotide sequences encoding those polypeptides. Those Examples are cited in MPEP section 1893.03(d) at page 1800-149, column 2 ("[n]ote also examples 1-17 of Annex B Part 2 of the PCT Administrative Instructions...")

Thus, in the present case, unity of invention exists at least as between any one of the claimed polypeptides SEQ ID NO:1-14, as recited in claims 1-2 of Group I, and the polynucleotide sequences which encode that particular polypeptide, as recited in claims 3-4 and 10-11 of Group II.

The Examiner has asserted that Groom *et al.* (the citation to which was omitted by the Examiner from the Restriction Requirement presently under response, and which reference was not included with that paper) and Ruben *et al.* (WO 98/39466) disclose one or more proteins with Groups I(A)-I(N), and that therefore unity of invention as between the claims of Groups I and II is thereby destroyed. See page 5, lines 4-10 of the Restriction Requirement. Applicants disagree, and respectfully submit that, even assuming ***solely*** for the sake of argument that any of the claimed polypeptides are disclosed by either of those references, the existence of Unity of Invention is not destroyed as between the other, undisclosed polypeptides and the corresponding polynucleotides, and that therefore simultaneous examination of any of those undisclosed polypeptides and their corresponding polynucleotides would still be required.

Therefore, Applicants respectfully request that the Examiner withdraw the Restriction Requirement at least as between each individual claimed polypeptides recited in claims 1-2 of Group I), and the polynucleotides encoding that polypeptide as recited in claims 3-4 and 10-11 of Group II, and examine those claims in a single application.

Unity of invention exists with respect to dependent claims in the same claim category as the independent claim from which they depend

MPEP section 1850(A) and 1893.03(d), which recite the provisions of paragraph (c) of Part 1 (entitled "Instructions Concerning Unity of Invention") of Annex B (entitled "Unity of Invention") to the Administrative Instructions Under the PCT, provides:

> **(A) Independent and Dependent Claims.**
>
> Unity of invention has to be considered in the first place only in relation to the independent claims in an international application and not the dependent claims. By "dependent" claim is meant a claim which contains all the features of another claim and is in the same category of claim as that other claim (the expression "category of claim" referring to the classification of claims according to the subject matter of the invention claimed for example, product, process, use or apparatus or means, etc.).
>
> (i) If the independent claims avoid the prior art and satisfy the requirement of unity of invention, no problem of lack of unity arises in respect of any claims that depend on the independent claims. In particular, it does not matter if a dependent claim itself contains a further invention....

See MPEP section 1850(A) at page 1800-61. See also MPEP Appendix AI at page 53.

In the present case, there is unity of invention as to both independent claim 1 and independent claim 10, as discussed above; moreover, both avoid the prior art as to the polypeptides undisclosed by the prior art, as discussed below. Finally, dependent claims 3-6 of Group II and claim 7 of Group III are product claims which, by virtue of the subject matter they recite and their ultimate dependence from claim 1, contain every feature of the independent claim from which they depend.

Thus, it is improper to restrict claim 7 (Group III) from the claims of Group I (claims 1, 2, 15 and 16) and Group II (claims 3-6, 8 and 10-11), as the Examiner has done. Therefore, Applicants respectfully request that the Examiner withdraw the Restriction Requirement at least as to the composition of matter claims, and that at least those claims be considered together in a single application.

Unity of invention exists as between all of Applicants' claims

MPEP 1850 provides:

> Unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more special technical features. The term "special technical features" is defined as meaning those technical features that define a contribution which each of the

> inventions considered as a whole, makes over the prior art. The determination is made based on the contents of the claims as interpreted in light of the description and drawings. Annex B also contains examples concerning unity of invention.

Id at page 800-61.

MPEP 1893.03(d) similarly provides:

> A group of inventions is considered linked to form a single general inventive concept where there is a technical relationship among the inventions that involves at least one common or corresponding special technical feature. The expression special technical features is defined as meaning those technical features that define the contribution which each claimed invention, considered as a whole, makes over the prior art. For example, a corresponding technical feature is exemplified by a key defined by certain claimed structural characteristics which correspond to the claimed features of a lock to be used with the claimed key. Note also examples 1-17 of Annex B Part 2 of the PCT Administrative Instructions as amended July 1, 1992 contained in Appendix AI of the MPEP.

Id at page 1800-149.

In the present case, unity of invention exists among all of Applicants' claims. The claimed polypeptide sequences and the claimed polynucleotide sequences encoding them are corresponding technical features which are common to all of Applicants claims, which serve to technically interrelate all of Applicants' claims, and which define the contribution over the prior art made by each of them (see *infra*). Thus, all of Applicants' claims are linked to form a single general inventive concept, and Applicants are therefore entitled to prosecute all of their pending claims in a single national stage application.

> <u>The claimed polypeptide sequences, and the claimed polynucleotide sequences encoding those polypeptide sequences, are corresponding technical features that are common to all of Applicants' claims and that serve to technically interrelate them</u>

Applicants' claims recite *inter alia* the polypeptides SEQ ID NO:1-14, and polynucleotides encoding those polypeptides, which sequences include the polynucleotide sequences SEQ ID NO:15-28. See Table 1 of the specification. Applicants respectfully submit that the claimed polypeptide sequences SEQ ID NO:1-14, and the claimed polynucleotide sequences encoding them, are corresponding technical features, given that the former are encoded by the latter, and conversely, the latter encode the former.

Further, the claimed polypeptide and corresponding polynucleotide sequences are common to all of Applicant's claims, given that every claim refers to one or both either explicitly

or implicitly, by virtue of depending from a claim which makes an explicit reference to the claimed sequences.

Moreover, the claimed polypeptide and corresponding polynucleotide sequences serve to technically interrelate all of Applicants' claims. Applicants' composition of matter claims (1, 2, 10, 11, 16 and 17) are drawn to either the sequences themselves (1 and 2, drawn to polypeptide sequences, and 3-4 and 10-11, drawn to polynucleotide sequences), to compositions of matter which comprise the sequences as one element (5-7,drawn to recombinant polynucleotide sequences, transformed cells, and transgenic organisms, respectively, and 15, drawn to pharmaceutical compositions comprising the claimed polypeptides), or to compositions of matter wherein the claimed polypeptide sequences define the functional limits of the claimed subject matter (claim 10, drawn to antibodies which specifically bind a polypeptide of claim 1, and claims 18 and 20, drawn to pharmaceutical compositions comprising agonists and antagonists, respectively, of the claimed polyptides).

In Applicants' method claims, the claimed sequences serve as the product of the claimed method (claims 12-14, drawn to methods for detecting the claimed polynucleotides in a sample; and claim 23, drawn to a method of screening for compounds which modulate expression of the claimed polynucleotides); as a reagent for performing the method (claim 16, drawn to a treatment method which employs the claimed polypeptides; claims 17 and 20, drawn to methods of screening for agonists or antagonists, respectively, of the claimed polypeptides); or as both (claim 8, drawn to a method of producing the polypeptides of claim 1 using the polynucleotides which encode those polypeptides).

Therefore, the claimed polypeptide and polynucleotide sequences are corresponding technical features which are common to all of Applicants' claims, and which serve to technically interrelate them. It follows that all of Applicants' claims should be examined in the single Application currently under consideration.

<u>The Examiner's assertion that any of the claimed polypeptides are taught by Groom *et al.* and/or by Ruben *et al.* is unsupported</u>

The assertion that "a protein with Groups I(A) - I(N) is taught by Groom *et al.* [citation omitted by Examiner] and Ruben *et al.* (WO 98/39466)" is unsupported. The Examiner has

failed to specify which of the claimed protein(s), if any, is(are) taught by the cited references. The Examiner has failed to provide a copy of either of the cited references; indeed, no more than the name of the first author is provided with respect to the first of them. Nor has the Examiner provided Applicants with any alignments demonstrating the veracity of her allegation.

Applicants respectfully request that the Examiner specify which of Applicants' claimed polypeptides the aforementioned references have been cited against, in order that they may properly evaluate the assertion of anticipation.

Rejoinder

Applicants submit that Claim 23 (Group XII) and Claims 12-14 (Group V) are methods of using the polynucleotides of Group II, which should be examined together with the polynucleotides of Group II, per the Commissioner's Notice in the Official Gazette of March 26, 1996, entitled "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)" which sets forth the rules, upon allowance of product claims, for rejoinder of process claims covering the same scope of products.

Applicants believe that no fee is due with this communication. However, if the USPTO determines that a fee is due, the Commissioner is hereby authorized to charge Deposit Account No. 09-0108.

Respectfully submitted,
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